

REMARKS/ARGUMENTS

Claims 44 and 70-73 have been revised to expressly recite the inherent feature of the claims, which relate to decreased gene expression based on a gene's methylation status.

No new matter has been introduced, and support for the claims as revised is provided by the application as filed. Entry of the revised claims is respectfully requested.

RESPONSE TO RESTRICTION

Reconsideration and modification or withdrawal of the Restriction Requirement is respectfully requested in light of the following remarks.

The Restriction Requirement asserts the following Groups:

Group I, claims 8-11, 15-18, 20-22, 25-27, 29-31, 54, 56, 58-62 and 68-69;

Group II, claims 8-9, 12-13, 15-17, 19-22, 25-26, 28-31, 56 and 68-69;

Group III, claims 33, 35-36, 40, 42-43, 63, 65, and 67;

Group IV, claims 33, 37-38, 40, 46-47, and 63;

Group V, claims 33, 35-36, 40, 42-43, 55, 63 and 66;

Group VI, claims 33, 37-38, 40, 46-47, and 63;

Group VII, claims 7, 14, 23, 32, 39, 44, and 70-73;

Group VIII, claims 7, 14, 23, 32, 39, 44 and 70-73.

Claims 7, 14 and 23 are alleged to link Groups I and II while claims 32 and 39 are alleged to link Groups II through VI.

The Restriction Requirement further states that "the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability..." (see bridging paragraph, pages 11-12 of the Restriction Requirement).

Applicants understand the above to indicate that should Group I or Group II be elected, linking claims 7, 14, and 23 will be examined with the elected Group and should the

linking claims be found allowable, the claims of the remaining Group will be rejoined. Similarly, Applicants understand that should any one of Groups II through VI be elected, linking claims 32 and 39 will be examined with the elected Group and should the linking claims be found allowable, the claims of all remaining Groups will be rejoined.

Applicants note, however, that there appears to be no recognition that if Groups I and II are linked while Groups II through VI are linked, then Groups I and III through VI must also be linked. Therefore, if Groups I and II are rejoined, then the correspondingly linked claims of Groups III through VI must also be rejoined. If this understanding is incorrect, Applicants respectfully request clarification and an explanation in the next Official Communication.

Additionally, and should the above understanding be incorrect, Applicants respectfully traverse the assertion of Groups I and II as separate inventions that are “linked inventions.” Applicants point out that the alleged separation of the claims into Groups I and II appears to reflect a failure to recognize *the presence of genus claims*. For example, and contrary to the asserted Restriction Requirement, claims 7-9, 14-16, 20-23, 25, 29-33, 39, 40, 56, 63, and 68-69 are *genus claims that do not require a feature of detection by nucleic acid, polypeptide, or methylation status as alleged in the restriction requirement*.

The fact that these claims appear in more than one of the asserted Groups as listed in the Restriction Requirement (and listed above) further supports the fact that these claims are genus claims. For example, many of these claims are listed in both of Groups I and II, or each of Groups III through VI, or both of Groups VII and VIII.

The alleged separation of the claims into these various Groups is thus a separation into the alleged species of detection by nucleic acid, polypeptide, or methylation status, *but without recognition of the genus claims*.

Recognition of the presence of genus claims is important because Applicants regard the genus as their invention. Any attempt to restrict the genus to be merely species thereof would deny Applicants the ability to seek claims directed to what they regard as the invention. See *In re Weber* (580 F.2d 455, 198 USPQ 328 (CCPA 1978)) and *In re Haas* (580 F.2d 461, 198 USPQ 334 (CCPA 1978)), and the discussion at MPEP 803.02. These decisions

clearly set forth that a restriction requirement cannot be used to divide a single claim, such as a genus claim. Therefore, and by way of example, claims 7-9, 14-16, 20-23, 25, 29-33, 39, 40, 56, 63, and 68-69 cannot be divided by restriction.

In light of the above arguments, and should the understanding of the prosecution of “linked inventions” indicated above be incorrect, Applicants respectfully request reconsideration and modification of the instant Restriction Requirement in favor of one group comprising the pending claims with recognition of genus claims 7-9, 14-16, 20-23, 25, 29-33, 39, 40, 56, 63, and 68-69.

In the event that the above understanding regarding “linked inventions” be correct, or the Restriction Requirement is nevertheless maintained, Applicants elect Group I, claims 8-11, 15-18, 20-22, 25-27, 29-31, 54, 56, 58-62 and 68-69, with traverse for the reasons provided above.

Additionally, and with respect to the Requirement for “one specific polynucleotide/polypeptide combination to which the claims will be restricted”, Applicants again respectfully elect the combination of HoxB13 expression and IL17BR expression as a ratio thereof. This combination is reflected in claims 7-23, and 25-31, for example. In light of the additional comments in the Restriction Requirement, Applicants elect SEQ ID NO:6 as a representative HoxB13 sequence and SEQ ID NO:1 as a representative IL17RB sequence in the combination.

Applicants point out that contrary to the assertions in the Restriction Requirement, the sequences featured in claims 54, 55, 58-62, and 65-67 are all either those of HoxB13 or IL17RB as encompassed by the genus claims. Accordingly, and because of the presence of genus claims, the attempt in the Restriction Requirement to assert that they are “different and distinct” is an improper attempt to avoid the standards reflected in *In re Weber* (580 F.2d 455 and *In re Haas* as well as the discussion at MPEP 803.02.

Therefore, Applicants respectfully submit that contrary to the characterization in the Restriction Requirement, the asserted “non-standard” requirement for election of subject

matter by sequence identifier is only proper if presented as a proper “election of species”. Otherwise, it is an improper attempt to restrict within a genus claims.

Moreover, and with respect to the assertions regarding the presence of combinations and subcombinations on pages 10-11 of the Restriction Requirement, Applicants strongly traverse the allegation that

“the combination as claimed does not require the particulars of the subcombination as claimed because clinical outcome ... can be assayed by determination of expression of HoxB13 alone, IL17RB alone or the combination (ratio) [of] HoxB13 and IL17RB.”

Simply put, the position reflected in the above claim is in error because the combination **does** require the particulars of the subcombinations because the combination expressly features, and so requires, the expression of HoxB13 and IL17RB. The fact that there are other methods that may be practiced with only HoxB13 or IL17RB does not change the fact that the combination requires the particulars of both.

Applicants point out that the above quote appears to have created a single criterion from the standard of 1) combination not requiring the particulars of the subcombination and 2) the subcombination has utility by itself. The above quote seems to say that because 2) is satisfied, 1) is satisfied because the combination would not require the particulars of the subcombination. This is in error and should be expressly recognized as such in the next Official Communication.

Furthermore, and because the standard for restriction between in cases of a combination/subcombination set forth at MPEP 806.05(c) are not met, Applicants respectfully point out that the invention of claims 7-23 and 25-31 may be viewed as a combination relative to the invention of at least claims 32-33, 35-40, 42-44, 46-47, 63, and 65-67, which feature a subcombination thereof.

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PATENT

CONCLUSION

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6151.

Respectfully submitted,



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